

§ 522.23

- 522.1884 Prednisolone sodium succinate injection.
- 522.1885 Prednisolone tertiary butylacetate suspension.
- 522.1890 Sterile prednisone suspension.
- 522.1920 Prochlorperazine, isopropamide for injection.
- 522.1940 Progesterone and estradiol benzoate.
- 522.1962 Promazine hydrochloride.
- 522.2002 Propiopromazine hydrochloride injection.
- 522.2005 Propofol injection.
- 522.2012 Prostalene solution.
- 522.2063 Pyrillamine maleate injection.
- 522.2076 Romifidine.
- 522.2100 Selenium, vitamin E injection.
- 522.2112 Sometribove zinc suspension.
- 522.2120 Spectinomycin dihydrochloride injection.
- 522.2121 Spectinomycin sulfate solution.
- 522.2150 Stanozolol sterile suspension.
- 522.2200 Sulfachlorpyridazine.
- 522.2220 Sulfadimethoxine injection.
- 522.2240 Sulfaethoxypyridazine.
- 522.2260 Sulfamethazine injectable solution.
- 522.2340 Sulfomyxin.
- 522.2404 Thialbarbitone sodium for injection.
- 522.2424 Sodium thiamylal for injection.
- 522.2444 Sodium thiopental implantation or injectable dosage forms.
- 522.2444a Sodium thiopental for injection.
- 522.2444b Sodium thiopental, sodium pentobarbital for injection.
- 522.2470 Tiletamine hydrochloride and zolazepam hydrochloride for injection.
- 522.2471 Tilmicosin.
- 522.2474 Tolazoline hydrochloride injection.
- 522.2476 Trenbolone acetate.
- 522.2477 Trenbolone acetate and estradiol.
- 522.2478 Trenbolone acetate and estradiol benzoate.
- 522.2483 Sterile triamcinolone acetonide suspension.
- 522.2582 Triflupromazine hydrochloride injection.
- 522.2610 Trimethoprim and sulfadiazine sterile suspension.
- 522.2615 Tripelennamine hydrochloride injection.
- 522.2640 Tylosin injectable dosage forms.
- 522.2640a Tylosin injection.
- 522.2662 Xylazine.
- 522.2670 Yohimbine injectable.
- 522.2680 Zeranol.
- 522.2690 Zinc gluconate.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13858, Mar. 27, 1975, unless otherwise noted.

21 CFR Ch. I (4–1–05 Edition)

§ 522.23 Acepromazine maleate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of acepromazine maleate.

(b) *Conditions of use.* See No. 000010, 000856 and 059130 in §510.600(c) of this chapter for use in dogs, cats, and horses as follows:

(1) *Indications for use.* It is used in dogs, cats, and horses as a tranquilizer.

(2) *Amount.* Dogs: 0.25 to 0.5 milligram per pound of body weight; Cats: 0.5 to 1.0 milligram per pound of body weight; Horses: 2.0 to 4.0 milligrams per 100 pounds of body weight.

(c) *Conditions of use.* See No. 000010 in §510.600(c) of this chapter for use in dogs as follows:

(1) *Indications for use.* It is used in dogs as an aid in tranquilization and as a preanesthetic agent.

(2) *Amount.* Dogs: 0.25 to 0.5 milligram per pound of body weight.

(3) *Limitations.* The drug is administered intravenously, intramuscularly or subcutaneously with the dosage individualized depending upon the degree of tranquilization required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 43831, Sept. 1, 1981, as amended at 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997; 68 FR 33856, June 6, 2003; 69 FR 33840, June 17, 2004]

§ 522.44 Sterile sodium acetazolamide.

(a) *Specifications.* Sterile sodium acetazolamide contains acetazolamide sodium complying with United States Pharmacopeia as a sterile powder with directions for reconstituting the product with sterile distilled water to furnish a product having a concentration of 100 milligrams acetazolamide activity per milliliter.

(b) *Sponsor.* See No. 010042 in §510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an aid in the treatment of dogs with mild congestive heart failure and for rapid reduction of intraocular pressure.¹

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may

Food and Drug Administration, HHS

§ 522.62

(2) It is administered intramuscularly or intraperitoneally to dogs at a level of 5 to 15 milligrams per pound of body weight daily preferably administered in two or more divided doses.¹

(3) For use only by or on the order of a licensed veterinarian.¹

§ 522.46 Alfaprostol.

(a) *Specifications.* Each milliliter of sterile solution contains 1 milligram of alfaprostol.

(b) *Sponsor.* No. 055882 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used in horses as follows:

(1) *Amount.* For average mature mares, 6.0 micrograms per kilogram of body weight.

(2) *Indications for use.* To cause luteolysis in mares with active corpora lutea.

(3) *Limitations.* For intramuscular or subcutaneous use as a single injection. Not for horses intended for food. Alfaprostol is readily absorbed through the skin and can cause abortion and/or bronchial spasms. Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 43300, Sept. 23, 1983, as amended at 53 FR 40057, Oct. 13, 1988]

§ 522.56 Amikacin sulfate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of amikacin (as the sulfate).

(b) *Sponsor.* See Nos. 000856 and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* 5 milligrams per pound of body weight twice daily.

(2) *Indications for use.* The drug is used in dogs for treatment of genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli* and *Proteus* spp. and skin and soft tissue infections caused by susceptible strains of *Pseudomonas* spp. and *E. coli*.

require bioequivalency and safety information.

(3) *Limitations.* The drug is administered intramuscularly or subcutaneously. Treat dogs with skin and soft tissue infections for a minimum of 7 days and those with genitourinary infections for 7 to 21 days or until culture is negative and asymptomatic. If no response is observed after 3 days of treatment, therapy should be discontinued and the case re-evaluated. Maximum duration of therapy should not exceed 30 days. Systemic aminoglycoside therapy is contraindicated in dogs with seriously impaired renal function. Not for use in breeding dogs as reproductive studies have not been conducted. Use with extreme caution in dogs in which hearing acuity is required for functioning. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[52 FR 11816, Apr. 13, 1987; 52 FR 15412, Apr. 28, 1987, as amended at 53 FR 27851, July 25, 1988; 62 FR 23357, Apr. 30, 1997]

§ 522.62 Aminopentamide hydrogen sulfate injection.

(a) *Chemical name.* 4-(Dimethylamino)-2,2-diphenylvaleramide hydrogen sulfate.

(b) *Specifications.* It is sterile and each milliliter of aqueous solution contains 0.5 milligram of the drug.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is intended for use in dogs and cats only for the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

NOTE: Not for use in animals with glaucoma because of the occurrence of mydriasis.

(2) Dosage is administered by subcutaneous or intramuscular injection every 8 to 12 hours, as follows:

Weight of animal in pounds	Dosage in milligrams
Up to 10	0.1
11 to 20	0.2
21 to 50	0.3
51 to 100	0.4
Over 100	0.5

Dosage may be gradually increased up to a maximum of five times the suggested dosage. Following parenteral